### **Minutes of Meeting**

# Alabama Medicaid Agency Pharmacy and Therapeutics Committee September 10, 2008

Attendees: Chairman Dr. Joseph Thomas, Dr. Michelle S. Freeman, Ms. Vicki Little Faulk, Dr. Kelli Littlejohn, Mr. Ben Main, Dr. Robert Moon, Dr. Nancy J. Sawyer, and Dr. Chivers R. Woodruff, Dr. Lucy Culpepper, Dr. Chad Bissell, and Dr. Laureen Biczak

Absent: Dr. Gerard J. Ferris

#### 1. OPENING REMARKS

Vice-chairman Main called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:00 a.m.

#### 2. APPROVAL OF MINUTES

Vice-chairman Main asked if there were any corrections to the minutes from the May 14, 2008 P&T Committee Meeting.

Dr. Thomas asked that the Positive Antipsychotic Project Workgroup report on page 1, last paragraph be amended to state "psychiatrists" rather than "psychologists".

There were no objections. A motion was made and seconded to approve the minutes with the correction.

#### 3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn announced that the federal requirement of all three characteristics related to Tamper Resistant prescriptions will take effect on October 1, 2008. More information concerning this can be found on the Agency's website.

Dr. Littlejohn provided an update on two Pharmacy Program projects. The cost of dispensing survey is completed; Health Information Designs (HID) has shared the preliminary results with the Pharmacy Associations. The verification process is underway. Also, the state Maximum Allowable Cost (SMAC) project has completed the first round of invoice gathering with 100% compliance. Myers and Stauffer is currently inputting the data; more information will be available this fall.

A Positive Antipsychotic Management (PAM) update was provided and it was noted that, as requested by the P&T Committee, the Agency has met with the PAM workgroup which includes Department of Mental Health, a group of child psychiatrists, and other specialists. At the last meeting, there was a request for a medical chart review of children identified by the PAM

project, which is underway. Mr. Main inquired as to whether Dr. Thomas Geary was part of the group. Dr. Littlejohn responded that the Agency would look into it. Dr. Moon added that Blue Cross had been contacted for involvement. Dr. Sawyer requested that the P&T committee be presented the final report information.

Dr. Littlejohn introduced Goold Health Systems as the new Clinical Services vendor for Alabama Medicaid Pharmacy. Dr. Chad Bissell and Dr. Laureen Biczak from Goold Health Systems were introduced. HID was awarded the Alabama Medicaid Administrative Services contract.

Dr. Littlejohn also announced that, in keeping with the P & T Committee's previous recommendations, Alabama Medicaid will follow current CDC recommendations and make Relenza and Tamiflu preferred as of Oct 1, 2008 throughout the duration of the flu season.

# 4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES (prior to each respective class review)

Five-minute verbal presentations were made on behalf of one pharmaceutical manufacturer. Dr. Littlejohn explained the process and timing system for the manufacturers' oral presentations. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class.

# **5. PHARMACOTHERAPY CLASS REVIEWS (Please refer to the web site for full text reviews.)**

The pharmacotherapy reviews began at approximately 9:10 a.m.

## Central α-Agonists Single Entity Agents AHFS 240816 Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the clinical packet including the fact that a brand form of methyldopa, Aldomet, is no longer available. He reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out there had been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new studies added to the evidence based review since the last review of this class. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity central  $\alpha$ -agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Dr. Woodruff asked about the transdermal form of clonidine for patients unable to swallow or are in long term care facilities. Dr. Littlejohn stated the patch formulation is available thru the medical justification process, and that many nursing home patients are now covered by Medicare Part D. Mr. Main pointed out that these were re-reviews of most of these drug classes. Dr. Sawyer asked for clarification on methyldopa not being available and Dr. Bissell clarified that the brand version of methyldopa, Aldomet, is no longer available while the generic is available.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

## Central α-Agonists Combination Products AHFS 240816

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the clinical packet. He reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out there had been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new studies added to the evidence based review since the last review of this class. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination central  $\alpha$ -agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Dr. Woodruff asked if there are any over the counter products in this class related to the language in the conclusion section of the review. Dr Bissell replied there were no OTCs available in this class. Dr. Littlejohn stated that the language with regard to this issue will be updated in the future. Mr. Main stated that historically this language was to prevent the idea of restricting access in Medicaid for these types of covered products.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

### **Direct Vasodilators Single Entity Agents AHFS 240820**

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out there had been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new

studies added to the evidence based review since the last review of this class. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity direct vasodilator is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots

### **Direct Vasodilators Combination Products AHFS 240820**

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out there had been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He did point out specifically that the individual components of the combo drug of hydralazine and isosorbide dinitrate (BiDil) are not interchangeable but that the individual components are available generically to allow titration. He pointed out that there have been no new studies added to the evidence based review since the last review of this class. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination direct vasodilator is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

## Peripheral Adrenergic Inhibitors AHFS 240832

<u>Manufacturer comments on behalf of these products:</u> None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out there had been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new studies added to the evidence based review since the last review of this class. He highlighted information from the clinical packet as to the place in therapy for these agents based on the

various evidence based guidelines that are listed in the clinical packet. The full text of the clinical packet is available on the website.

No brand peripheral adrenergic inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

## **Miscellaneous Hypotensive Agents AHFS 240892**

Manufacturer comments on behalf of these products:

None

Dr. Chad Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out there had been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new studies added to the evidence based review since the last review of this class. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The full text of the clinical packet is available on the website.

No brand miscellaneous hypotensive agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Dr. Culpepper asked if anyone ever uses this drug class anymore. Dr. Littlejohn stated it there was some utilization on the drug during the past year.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

#### α-Adrenergic Blocking Agents AHFS 242000

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from information in the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review and the one updated evidence based guideline included in the packet since the last review and directed Committee members to the location of the four new trials in the review. He pointed out that the ALLHAT trial is the only large trial to date that studied the effects on cardiovascular morbidity and morbidity of  $\alpha_1$ -blockers compared with the other classes of antihypertensive drugs. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets

have not changed since the last review. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The full text of the clinical packet is available on the website.

No brand  $\alpha$ -adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

# β-Adrenergic Blocking Single Entity Agents AHFS 242400

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review. He pointed out the new drugs available in this class since the last review and pointed out the changes in clinical guidelines for these agents since the last review. These included Coreg CR®, Bystolic®, and a generic form of carvedilol. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He highlighted the six new evidence based studies since the last review and directed Committee members to these studies in the clinical packet. He highlighted information as to the place in therapy of for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity  $\beta$ -adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Dr. Sawyer asked if Kerlone has been removed from the market as she has recently received calls regarding the drug not being available. Dr. Bissell and Dr. Littlejohn were not aware of any issues. Mr. Main thanked Dr. Bissell for pointing out the new information in the reviews since the last time the drug classes were reviewed and asked that this be continued.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

# **β-Adrenergic Blocking Agents Combination Products AHFS 242400**<u>Manufacturer comments on behalf of these products:</u> None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He stated that the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since

the last review. He pointed out that there was no new evidence based studies added to the review since the last time. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination  $\beta$ -adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agent.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

### **Dihydropyridines Single Entity Agents AHFS 242808**

Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He noted that generic forms of amlodipine and felodipine had become available since the last time the class was reviewed, as well as the availability of generic Sular since the clinical packet was printed. He pointed out the changes in clinical guidelines for these agents since the last review. He stated that the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been five new studies added to the review since the last time, including the ALLHAT trial. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity dihydropyridine calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

## **Dihydropyridines Combination Products AHFS 242808**

Manufacturer comments on behalf of these products: None

This is a new category. Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out that generics of the combination products are not currently available. He stated that the combination products in this review are not specifically mentioned in any of the evidence based guidelines. He noted that since the clinical packets were printed Exforge (amlodipine and valsartan) has gained FDA approval as a first line treatment option for hypertension. He briefly reviewed the kinetics and adverse effects of these agents. He pointed out that there have been

five new studies. He highlighted the COACH trial that compares amlodipine versus olmesartan versus each possible combination of above. The study reported all combinations reduced seated diastolic blood pressure significantly greater than either component as monotherapy at the same dosage. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination dihydropyridine calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

### Miscellaneous Calcium-Channel Blocking Agents 242892

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He stated that the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there has been one new study added to the review since the last time and directed Committee members to it in the clinical packet. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are included in the clinical packet. The clinical packet is available in full text on the website.

No brand miscellaneous calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

# **Angiotensin-Converting Enzyme Inhibitors Single Entity Agents AHFS 243204**

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He stated that the indications, kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been four new studies added to the evidence based reviews since the last time this category was reviewed and

directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity angiotensin-converting enzyme inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

# **Angiotensin-Converting Enzyme Inhibitors Combination Products AHFS 243204**

<u>Manufacturer comments on behalf of these products:</u> None

Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He stated that the indications, kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been four new studies added to the evidence based review since the last time. Dr. Bissell reviewed the highlights of these new studies, and directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination angiotensin-converting enzyme inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice-Chairman Main asked the P&T Committee Members to mark their ballots.

# Angiotensin II Receptor Antagonists Single Entity Agents AHFS 243208 Manufacturer comments on behalf of these products: Cozaar® (losartan) - Merck

Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He stated that the indications, kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been nine new studies added to the evidence based review since the last time, reviewed highlights of these new studies, and directed Committee members to their packets for

this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity angiotensin II receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Dr. Culpepper asked if the drugs on the PDL will continue as is. Dr. Littlejohn stated that it was possible the current PDL could change based on contract terms and expirations and the financial review (after the P&T clinical recommendations).

There were no further discussions on the agents in this class. Chairman Thomas (who joined the Committee) asked the P&T Committee Members to mark their ballots.

# Angiotensin II Receptor Antagonists Combination Products AHFS 243208 Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He pointed out that there had been one change since the time the clinical packet was last printed. The combination of valsartan and hydrochlorothiazide has been approved for first line therapy for patients with hypertension. He noted the kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been seven new studies added to the evidence based review since the last time, reviewed highlights of these new studies, and directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination angiotensin II receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

# Mineralocorticoid (Aldosterone) Receptor Antagonists Single Entity Agents AHFS 243220 Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug

events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been six new studies added to the evidence based review since the last time, reviewed highlights of these new studies, and directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity mineralocorticoid (aldosterone) receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands

Dr. Thomas clarified with Dr. Bissell regarding the adverse reaction section was cirrhosis of the liver.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

# Mineralocorticoid (Aldosterone) Receptor Antagonists Combination Products AHFS 243220

Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new studies added to the evidence based review since the last time. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination mineralocorticoid (aldosterone) receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

### Renin Inhibitors Single Entity Agents AHFS 243240

Manufacturer comments on behalf of these products:

None

This is a new class. Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He

pointed out that at this time, because this is a new agent and a new class of drugs, none of the treatment guidelines have incorporated the use of renin inhibitors either as a single entity product or a fixed dose combination. He noted the black box warnings with regards to usage of the only product in this class during pregnancy. He highlighted the study by Strasser that compared aliskiren to lisinopril and highlighted that aliskiren showed similar reductions from baseline to lisinopril in mean sitting diastolic blood pressure. He pointed out that no current evidence based guidelines provide guidance as to the place of this class in therapy. The clinical packet is available in full text on the website.

No brand single entity renin inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

Dr. Woodruff pointed out the various studies that compared aliskiren to ACE and ARBs that suggested aliskiren had significantly better reductions in blood pressure. Dr. Bissell pointed out that no clinical outcome data is available for the products in this review. Dr. Woodruff asked if aliskiren would be available and Dr. Littlejohn responded that it is currently available with medical justification.

Mr. Main commented that if any drug has a new black box warning whether the class was being reviewed or not, it should be discussed at the next available review of that class. Dr. Thomas stated that he thought it would be a good idea to discuss the black box warnings regardless of when the class is due for review again. Mr. Main and Dr. Thomas requested that the Committee be notified of any new black box warning at the next meeting regardless of whether the class is re-reviewed. After discussion, it was agreed that the Alabama Medicaid Agency will notify Committee members collectively by email of any new black box warnings. and the Committee would make a recommendation if a review of the class is warranted at the next available meeting. In addition, a new section will be included in the review packet to list a collection of all black box warnings since the last meeting.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

### **Renin Inhibitors Combination Products AHFS 243240**

Manufacturer comments on behalf of these products:

None

This is a new class. Dr. Bissell reviewed highlights of the overview, indications, formulations, and pharmacology of the products included in this review directly from the clinical packet. He pointed out that none of the guidelines currently contain information with regards to this class. He noted the black box warnings with regards to usage of the only product in this class during pregnancy. He highlighted the one new study (Villamel). He pointed out that no current evidence based guidelines provide guidance as to the place of this agent in therapy. The clinical packet is available in full text on the website.

No brand combination renin inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

### **Loop Diuretics AHFS 402808**

Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out that there have been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been two new evidence based studies added to the evidence based review since the last time and directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand loop diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

## Potassium-sparing Diuretics Single Entity Agents AHFS 402816 Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out that there have been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events; drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new evidence based studies added to the evidence based review since the last time the class was reviewed. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand single entity potassium-sparing diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

### **Potassium-sparing Diuretics Combination Products AHFS 402816**

Manufacturer comments on behalf of these products:

None

Dr. Bissell reviewed highlights of the overview, indications, and formulations, of the products included in this review directly from the clinical packet. He pointed out the there have been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, black box warnings and dosing and administration sections of these packets have not changed since the last review. He pointed out that there have been no new evidence based studies added to the evidence based review since the last time the class was reviewed. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand combination potassium-sparing diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

### **Thiazide Diuretics AHFS 402820**

Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out the changes in clinical guidelines for these agents since the last review; both of which specifically mention thiazide diuretics for use in HTN. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there has been one new evidence based study added to the evidence based review since the last time and directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand thiazide diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

### Thiazide-like Diuretics AHFS 402824

Manufacturer comments on behalf of these products: None

Dr. Bissell reviewed highlights of the overview, indications, and formulations of the products included in this review directly from the clinical packet. He pointed out there have been no changes in clinical guidelines for these agents since the last review. He noted the kinetics, adverse drug events, drug interactions, and dosing and administration sections of these packets have not changed since the last review. He pointed out that there has been one new study added to the evidence based review since the last time and directed Committee members to their packets for this information. He highlighted information from the clinical packet as to the place in therapy for these agents based on the various evidence based guidelines that are listed in the clinical packet. The clinical packet is available in full text on the website.

No brand thiazide-like diuretics is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

There were no questions. Mr. Main had a comment. He mentioned that some legend drugs have moved to OTC and that we should be careful of changing the language in the recommendations section to allow for such movements. Dr. Littlejohn and Dr. Moon explained the language will include the words, "if available."

There were no further discussions on the agents in this class. Chairman Thomas asked the P&T Committee Members to mark their ballots.

#### 7. RESULTS OF VOTE ANNOUNCED

Dr. Littlejohn announced the results of voting for each of the therapeutic classes and announced that all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

### 8. NEW BUSINESS

Dr. Thomas stated that the Committee needed to select a new vice chair; Dr. Thomas and Dr. Culpepper were eligible. Dr. Littlejohn reminded the members that to be eligible, Committee members must be on the board for one year. Dr. Thomas declined the nomination. Mr. Main seconded the motion for the sole candidate. Dr. Culpepper accepted. Dr. Thomas called for a vote and there was unanimous approval. The new chair (Mr. Main) and co-chair (Dr. Culpepper) will take their positions October 1, 2008. Dr. Littlejohn thanked Dr. Thomas for his dedicated services as Chair of the Committee and mentioned there is a new pharmacist member for the upcoming term.

### 9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for 9:00 a.m. on December 10, 2008 at the Alabama State Capitol Auditorium. The next meeting is scheduled for February 11, 2009 (location to be announced).

# 10. ADJOURN

There being no further business,

The meeting was adjourned at 11:41 a.m.

# Appendix

### RESULTS OF THE BALLOTING

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
September 10, 2008

A. Recommendation: No brand single entity central  $\alpha$ -agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents. Amendment: None Vote: Unanimous to approve as recommended Approve Approve as amended Disapprove No action the full Approve Approve as amended Disapprove Disapprove No action Commissioner B. Recommendation: No brand combination central  $\alpha$ -agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents. Amendment: None Vote: Unanimous to approve as recommended Approve Approve as amended Disapprove No action Medical Director Approve Approve as amended Disapprove No action Deputy Commissioner Approve Approve as amended Disapprove No action

Commissioner

status. Alabama Me	dicaid should ac	entity direct vasodilator is cept cost proposals from n gnate one or more preferre	nanufacturers to de	
Amendment: None	e			
Vote: Unanimous to	o approve as rec	ommended		
2 Moorno	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Medical Director				
Deputy Commissioner	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Carolle	Approve	Approve as amended	☐ Disapprove	☐ No action
Commissioner				
status. Alabama Med	dicaid should acoud possibly design	nation direct vasodilator is cept cost proposals from m gnate one or more preferred	anufacturers to de	THE RESERVE OF THE PARTY OF THE
Vote: Unanimous to	approve as reco	ommended		
	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Medical Director				
Kathy Hall	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	10			
Cerolle d	Approve	Approve as amended	☐ Disapprove	☐ No action
Commissioner				

effective products ar	nd possibly desi	gnate one or more preferre	ed agents.	
Amendment: None				
Vote: Unanimous to	approve as rec	ommended		
PMoormo	Approve	☐ Approve as amended	Disapprove	☐ No action
Medical Director				
Deputy Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action
Carol D	Approve	Approve as amended	Disapprove	□ No action
Commissioner			Disapprove	
preferred status. Alai	bama Medicaid ive products and	ellaneous hypotensive agen should accept cost proposa d possibly designate one of	als from manufactu	irers to
Vote: Unanimous to	approve as reco	ommended		
P-Mon Mn Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action
1	Approve	Approve as amended	☐ Disapprove	☐ No action

E. Recommendation: No brand peripheral adrenergic inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost

G. Recommendation: No brand α-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.
Amendment: None
Vote: Unanimous to approve as recommended
Approve Approve as amended Disapprove No action
Medical Director
Deputy Commissioner Approve Approve as amended Disapprove No action
Approve
Commissioner
<b>H. Recommendation:</b> No brand single entity $\beta$ -adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.
Amendment: None
Vote: Unanimous to approve as recommended
Approve Approve Disapprove No action
Medical Director
Approve Approve as amended Disapprove No action
Deputy Commissioner
Approve  Approve as amended  Disapprove  No action
Commissioner

determine cost effective products and possibly designate one or more preferred agent.
Amendment: None
Vote: Unanimous to approve as recommended
Approve Approve as amended Disapprove No action
Mediçal Director
Deputy Commissioner
Cerel Disapprove
Commissioner
is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.  Amendment: None
Vote: Unanimous to approve as recommended
Approve Approve as amended Disapprove Disapprove No action Medical Director
Approve Approve as amended Disapprove Do No action
Deputy Commissioner
Approve Approve as amended Disapprove No action
Commissioner

I. Recommendation: No brand combination  $\beta$ -adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to

manufacturers to de preferred brands.	etermine cost effe	ective products and possib	ly designate one or	more
Amendment: Non	ie			
Vote: Unanimous	to approve as rec	ommended		
	Approve	☐ Approve as amended	Disapprove	☐ No action
Medical Director				
Nathy Hull	Approve	Approve as amended	Disapprove	☐ No action
Deputy Commissioner				
Centz	Approve	Approve as amended	☐ Disapprove	☐ No action
Commissioner				
recommended for p	referred status. A stermine cost effe	ellaneous calcium-channel clabama Medicaid should a ective products and possibl	accept cost proposa	
Vote: Unanimous t	o approve as rec	ommended		
PMOD MD  Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Kathy Hall	Approve	Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner  Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action
Commissioner				

K. Recommendation: No brand combination dihydropyridine calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from

M. Recommendation: No brand single entity angiotensin-converting enzyme inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.
Amendment: None
Vote: Unanimous to approve as recommended
PMonus Approve Approve as amended Disapprove No action
Medical Director
Mathy Welf
Deputy Commissioner
Approve Approve as amended Disapprove No action
Commissioner
N. Recommendation: No brand combination angiotensin-converting enzyme inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.
Amendment: None
Vote: Unanimous to approve as recommended
Approve as amended Disapprove Disapprove No action Medical Director
1 1111
Approve Approve as amended Disapprove No action
reputy Commissioner
Approve Approve as amended Disapprove No action
ommissioner

recommended for p	oreferred status. A	e entity angiotensin II rece Alabama Medicaid should a ective products and possible	accept cost propos	
Amendment: Non	ie			
Vote: Unanimous	to approve as rec	ommended		
PMOD MD	Approve	Approve as amended	☐ Disapprove	☐ No action
Medical Director				
Jolly Hell	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner				
Cense 22	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner				
recommended for p	referred status. A	ination angiotensin II receptable labama Medicaid should a ctive products and possible	ccept cost propos	
Amendment: Non	e			
Vote: Unanimous t	o approve as reco	ommended		
Phooms	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Medical Director	-		5.25	
July Hell	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner				
Cind &	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner				

antagonist is recom	mended for preferences to det	e entity mineralocorticoid ( erred status. Alabama Med termine cost effective prod	icaid should accep	ot cost
Amendment: Non	e			
Vote: Unanimous	to approve as rec	commended		
PMormo	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Medical Director				
Tathy Holl	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner				
Crol &	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner				
antagonist is recom	mended for prefe ufacturers to det	ination mineralocorticoid ( erred status. Alabama Medi ermine cost effective produ	caid should accep	t cost
Amendment: Non	e			
Vote: Unanimous t	o approve as rec	ommended		
PMG02 MD  Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Yathy Hall	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	(4)			
lens o	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner				

status. Alabama Me	dicaid should ac	e entity renin inhibitor is recept cost proposals from n gnate one or more preferre	nanufacturers to de	
Amendment: Non	e			
Vote: Unanimous t	o approve as rec	ommended		
PMODIND	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Medical Director				
	Approve	Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner				
Cend &	M Approve	Approve as amended	☐ Disapprove	☐ No action
Commissioner				
status. Alabama Med	dicaid should ac and possibly desig	ination renin inhibitor is re cept cost proposals from m gnate one or more preferred	nanufacturers to des	
Vote: Unanimous to	approve as rec	ommended		
P Mos un Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action
Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action

Medicaid should ac	cept cost propos	diuretic is recommended for als from manufacturers to or or more preferred brands.	The second secon	
Amendment: Non	e			
Vote: Unanimous t	o approve as rec	ommended		
PMODMO  Medical Director	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action
Cerol &	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner				
preferred status. Ala	bama Medicaid	e entity potassium-sparing of should accept cost proposa d possibly designate one or	ls from manufactu	irers to
Amendment: None				
Vote: Unanimous to	approve as reco	ommended		
Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Nothy Way Deputy Commissioner	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action

		should accept cost proposed possibly designate one of		
Amendment: Non	e			
Vote: Unanimous t	o approve as rec	ommended		
Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Yothy Hell	Approve	Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner  Complete Commissioner	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Alabama Medicaid	should accept cos nd possibly desig	de diuretic is recommende st proposals from manufac mate one or more preferred	turers to determine	
Vote: Unanimous t	o approve as reco	ommended		
PMGD MD  Medical Director	Approve	Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	Approve	Approve as amended	☐ Disapprove	☐ No action
Cind	Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner				

W. Recommendation: No brand combination potassium-sparing diuretic is recommended for

Alabama Medicaid	No brand thiazide-like diuretics is recommended for preferred should accept cost proposals from manufacturers to determine and possibly designate one or more preferred brands.	
Amendment: Non	e	
Vote: Unanimous	to approve as recommended	
	Approve	☐ No action
Medical Director		
nothy Well	Approve  Approve as amended  Disapprove	☐ No action
Deputy Commissioner		
Cho	Approve Approve as amended Disapprove	☐ No action
Commissioner		
Respectfully submitted:		
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Cur 11	· Personal Control of the Control of	
Chad Bissell, Pharm. D		Date
		#5.000°